DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JAN 1 0 2017

Mr. Uraiwan P. Labadini
Quality Assurance/Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

Re: K070654
Trade/Device Name: Belmont Hyperthermia Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: March 9, 2007
Received: March 9, 2007

Dear Mr. Labadini:

This letter corrects our substantially equivalent letter of June 8, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Belmont *Hyperthermia Pump*

Indications For Use:

The intended use of the Belmont *Hyperthermia Pump* is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K070154

K070654

Belmont Instrument Corporation

Creating a New Standard of Care

JUN - 8 2007

Registered in Accordance with ISO 13485

Premarket Notification
510(k) Summary
[As Required by 21 CFR 807.92(a)]

Date prepared: March 9, 2007

1. Submitter & Manufacturing Site: Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702

2. Contact Person: Uraiwan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214

3. Trade Name: The Belmont *Hyperthermia Pump*

4. Common name: Warmer, Thermal, Infusion Fluid

5. Classification name: Warmer, Thermal, Infusion Fluid

6. Product Code: 80 LGZ
Device Class: Class II

7. Performance Standards:
No performance standards have been officially adopted by the F.D.A.

8. The Belmont *Hyperthermia Pump* is substantially equivalent to the ThermoChem-HT System, which was the subject of Premarket Notification #K993330 and received F.D.A 510(k) concurrence to market on December 30, 1999.

9. Brief Description:

The Belmont *Hyperthermia Pump* combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid perfusion of warmed fluid. It can raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

The system monitors fluid temperature, patient temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid pumped, output fluid temperature, target temperature, patient temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation.

10. Intended Use

The intended use of the Belmont *Hyperthermia Pump* is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

11. Summary of the technological characteristics of the Belmont *Hyperthermia Pump* compared to the predicate device, ThermoChem-HT System.

These two devices have the same operating principle, energy type, environmental specifications, or performance specifications. These two devices use roller-type fluid pump, touch screen to direct the user through set-up and use, a disposable set including large fluid reservoir to circulate sterile fluid into and out of the body cavity. Flow from the patient outlet is drained into the large reservoir, then through a roller pump and then to a heat exchanger. The heat exchanger warms fluid to the desired target temperature and then passes to the body cavity through the patient line/return line. These systems also monitor the circulating sterile fluid temperature. The *Hyperthermia Pump* sounds an audible alarm, stops heating, and pumping at all unsafe conditions.

12. Summary of Nonclinical Tests and Results

In order to verify performance of the Belmont *Hyperthermia Pump* in support of substantial equivalence, the following tests were carried out:

a. The ability of the system to pump fluids accurately over the full range of flow rate and operating conditions including different input fluid temperatures, different back pressure, and change in ambient temperature.

b. The ability of the system to warm fluid to the desired target temperature over the full range of flow rate and operating conditions.

c. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, and other internal system malfunctions.

The Belmont *Hyperthermia Pump* performed within specification in all of the above tests.

13. Conclusion: The Belmont *Hyperthermia Pump* is substantially equivalent to the ThermoChem-HT System, a legally marketed devices intended to circulate warmed sterile fluid through the body cavity.